DATE 30 Sep 03

USAMMDA INFORMATION PAPER

PRODUCT: HEMOGLOBIN BASED OXYGEN CARRIER (HBOC)

DESCRIPTION: This product is a solution of hemoglobin polymer derived from either human or animal blood. Hemoglobin is the oxygen-carrying component of red blood cells. This product is designed to be used in the event of a massive hemorrhage resulting in the rapid loss of blood when whole blood is not available for transfusion. This product is more advantageous than whole blood since it is stable for months to a year at room temperature and for two years at $4^{o}C$ as compared to whole blood, which can be stored refrigerated for a maximum of 42 days. This product is also universally compatible and would not require blood typing prior to use.

PROGRAM RELEVANCE to the ARMY: This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports: "Shape the Security Environment," "Forcible Entry Operations," "Sustained Land Dominance" and "Support Civil Authorities." In any conflict of civilian disaster, it is an unfortunate fact that there will be casualties with severe bleeding. This product is intended to save soldiers' lives in those situations. The medic will use this product far forward to replace lost blood and allow the casualty to be evacuated to available medical assets further back, again reducing the logistical burden far forward. This product supports Future Operational Capability MD97-003 (Patient Treatment and Area Support), MD97-005 (Far-Forward Surgical Support), MD97-008 (Combat Health Logistics System [CHLS] and Blood Management).

ISSUES/ ACTIONS:

- Support for troops deployed in the war against terrorism and Operation Enduring Freedom (OEF)/ Operation Iraqi Freedom (OIF) increased the urgency in making this product available. There are at least three manufacturers of this product. None of these products are FDA approved. Each manufacturer has a product in a different level of development for different indications.
- Previous experience with products of this type and the toxicities associated with them will have to be addressed in order to continue development of this product. While none of these products under evaluation exhibit any toxicity, this is one area that the FDA will be very interested in and monitor closely.
- It is necessary for this product to be officially designated as a Contingency Protocol for Force Health Protection in order for this product to have the Human Subject Research Review Board designated the Investigational Review Board of record.
- There is no draft Operational Requirements Document (ORD). The Research Area Directorate has a Mission Needs Statement (MNS). Since this is not an Army developed item the need for a Joint Operational Requirements Document (JORD) is not required.
- There is no out year monetary support of this product. Present funding comes from a year-to-year congressional set-aside. Until this product is included in the POM transition of this product into advanced development cannot take place.
- Presently, the commercial market is developing this product with the DoD observing the development. It is not a DoD developmental item.

BPL #: 437
DA PROJECT/TASK: Combat Casualty Care
PE/PROJ 643807.836BC
MAMP RANK: NA
ARMY ORD:
CARDS#

SCHEDULE:
Decision Review 4QFY04

For additional information, contact: Pharmaceutical System Division, DSN 343-2051, Comm. 301-619-2051